## DETAILED ACTION

Claims 1-35 are pending.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, drawn to a method of diagnosing testicular seminomas (TS) or a predisposition to developing TS in a subject comprising determining an expression level of a TS-associated gene in a patient sample.

Group II, claim(s) 13, drawn to a TS reference expression profile, comprising a pattern of gene expression of two or more genes selected from the group consisting of TS 1-939.

Group III, claim(s) 14, drawn to a TS reference expression profile, comprising a pattern of gene expression of two or more genes selected from the group consisting of TS 1-346.

Group IV, claim(s) 15, drawn to a TS reference expression profile, comprising a pattern of gene expression of two or more genes selected from the group consisting of TS 347-939.

Group V, claim(s) 16 and 34, drawn to a screening method and compound.

Group VI, claim(s) 17, 19-20, and 34, drawn to a screening method and compound.

Group VII, claim(s) 18 and 34, drawn to a screening method and compound.

Group VIII, claim(s) 21-22, drawn to a kit/array comprising a detection reagent which binds to two or more nucleic acid sequences selected from the group consisting of TS 1-939.

Group IX, claim(s) 23, drawn to a method of treating or preventing TS in a subject comprising administering to said subject an antisense composition.

Group X, claim(s) 24-25, drawn to a method of treating or preventing TS in a subject comprising administering to said subject an siRNA composition.

Group XI, claim(s) 26, drawn to a method of treating or preventing TS in a subject comprising administering to said subject an antibody composition.

Group XII, claim(s) 27, drawn to a method of treating or preventing TS in a subject comprising administering to said subject a vaccine comprising a polypeptide encoded by a nucleic acid selected from the group consisting of TS1-346 (or a polynucleotide encoding the polypeptide).

Group XIII, claim(s) 28-29, drawn to a method of treating or preventing TS in a subject comprising administering to said subject a compound that increases the expression or activity of TS 347-939.

Group XIV, claim(s) 30, drawn to a method of treating or preventing TS in a subject comprising administering to said subject a pharmaceutically effective amount of polynucleotide selected from the group consisting of TS 347-939, or polypeptide encoded by thereof.

Group XV, claim(s) 31-32 and 35, drawn to a composition comprising an antisense polynucleotide or siRNA against a polynucleotide selected from the group consisting of TS 1-346.

Group XVI, claim(s) 33, drawn to a composition comprising an antibody that binds to a protein encoded by any one gene selected from the group consisting of TS 1-346.

The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

This PCT rule defines special technical features as technical features that identify a contribution which each of the claimed inventions, considered as a whole, makes over prior art. Independent Claim 1 is anticipated by prior art. Skotheim et al in "New insights into testicular germ cell tumorigenesis from gene expression profiling" (Cancer Research, Vol, 62, No 8; 15 April 2002, pages 2359-2364, whole document) teach a

method of diagnosing testicular carcinomas, including seminomas, in a subject comprising determining expression levels of TS-associated genes in biological samples (e.g. title, abstract and page 2359, ¶ 4-5). Therefore, claim 1 lacks a special technical feature and cannot share one with the other claims.

The claimed TS-associated gene expression diagnostic therefore does not represent an advance over the art and hence there is no unity of invention.

The compositions of Groups III and IV require distinct elements such as genes from TS 1-346 vs. TS 347-939. Group II is a subcombination to Group III and likewise to Group III. The methods of Groups I, V-VII and IX-XIV are distinct each from the other because each uses different, unrelated, method steps or uses distinct compositions. In addition, the compositions of Groups II-IV (expression profiles) are distinct from the composition of Groups VIII, XV and XVI which are nucleic acid probe arrays, antisense/siRNAs and antibodies, respectively. Each composition can be used in distinct methods and are composed of distinct chemical structures such as polynucleotides vs. proteins.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Possible Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See

MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Species Election***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. This application contains claims directed to the following patentably distinct species:

**-If Applicant elects Group I,**

-Applicant must further elect only one TS-associated gene from among the group consisting of TS 1-939 (e.g. Claims 2-4).

**-If Applicant elects Group II,**

-Applicant must further elect only one combination of two or more TS-associated genes from among the group consisting of TS 1-939 (e.g. Claim 13).

**-If Applicant elects Group III,**

-Applicant must further elect only one combination of two or more TS-associated gene from among the group consisting of TS 1-346 (e.g. Claim 14).

**-If Applicant elects Group IV,**

-Applicant must further elect only one combination of two or more TS-associated gene from among the group consisting of TS 347-939 (e.g. Claim 15).

**-If Applicant elects Group V,**

-Applicant must further elect only one type of polypeptide encoded by the group consisting of TS 1-939 (e.g. Claim 16).

**-If Applicant elects Group VI,**

-Applicant must further elect only one (or one combination of two or more) types of marker genes from among the group consisting of TS 1-939 (e.g. Claims 17 and 20).

**-If Applicant elects Group VII,**

-Applicant must further elect only one type of polypeptide encoded by the group consisting of TS 1-939 (e.g. Claim 18).

**-If Applicant elects Group VIII,**

-Applicant must further elect only one combination of two or more types of nucleic acid sequences selected from the group consisting of TS 1-939 (e.g. Claims 21-22).

**-If Applicant elects Group IX,**

-Applicant must further elect only one type of coding sequence selected from the group consisting of TS 1-346 (e.g. Claim 23).

**-If Applicant elects Group X,**

-Applicant must further elect only one type of nucleic acid sequence selected from the group consisting of TS 1-346 (e.g. Claim 24).

**-If Applicant elects Group XI,**

-Applicant must further elect only one type of gene selected from the group consisting of TS 1-346 (e.g. Claim 26).

**-If Applicant elects Group XII,**

-Applicant must further elect only one type of nucleic acid selected from the group consisting of TS 1-346 (e.g. Claim 27).

**-If Applicant elects Group XIV,**

-Applicant must further elect only one type of polynucleotide selected from the group consisting of TS 347-939 (e.g. Claim 30).

**-If Applicant elects Group XV,**

-Applicant must further elect only one type of polynucleotide selected from the group consisting of TS 347-939 (e.g. Claim 31).

**-If Applicant elects Group XVI,**

-Applicant must further elect only one type of gene selected from the group consisting of TS 1-346 (e.g. Claim 33).

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the reasons given above.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Hibbert, Ph.D., whose telephone number is 571-270-3053. The examiner can normally be reached on Monday-Friday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catherine S. Hibbert
Examiner/Art Unit 1636

/Daniel M Sullivan/
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